

REMARKS

Claims 1 to 51 are pending.

Present amendment revises Claims 1-51 and adds new Claims 52-74.

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Applicants introduce new Claims 52-74, defining combinations of therapeutic agents. Support for new Claims 52-74 is found, for example, in originally-filed Claims 1-51 and in the specification, as follows:

New Claims	Originally-Filed	Specification
52-74	Claims 1-51	Page(s) /Line(s))
52	7	P.21, L.2-11
53	12	P.21, L.2-11
54	13	P.21, L.2-11
55	14	P.21, L.2-11
56	15	P.21, L.2-11
57	16	P.21, L.2-11
58	17	P.21, L.2-11
59	18	P.21, L.2-11
60	19	P.21, L.2-11
61	20	P.21, L.2-11
62	7	P.21, L.2-11
63	--	P.35, L.5-9
64	--	P.35, L.5-9
65	6	P.10, L.26-P.11, L.2 and P.17, Compound #1
66	7	P.21, L.2-11
67	49	P.5, L.4-10
68	50	P.5, L.4-10
69	51	P.5, L.4-10
70	21	P.18, L.2-4
71	7	P.21, L.2-11

72	49	P.5,L.4-10
73	50	P.5,L.4-10
74	51	P.5,L.4-10

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The Office rejected originally filed Claims 1-51 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. More specifically, the Office asserts that "[t]he claims encompass a genus of compounds defined only by their function wherein the relationships between the structural features of the members of the genus and said function have not been defined. In absence of such a relationship either disclosed in the application or which would be based on the information readily available to one skilled in the art, the skilled artisan would not know how to make and use the invention that lacks structural definition." It appears that the primary focus of this argument is on Applicant's use of the terms "aldosterone receptor antagonist" and "beta-adrenergic antagonist" in the claims.

Applicants acknowledge that the terms "aldosterone receptor antagonist" and "beta-adrenergic antagonist" each define a genus of compounds by their function. Nonetheless, the terms are well-known to, and accepted by, those of skill in the art. Numerous validated methods for identifying compounds that are aldosterone receptor antagonists or beta-adrenergic antagonists have been disclosed in the literature and can be used by those of skill in the art to identify specific compounds falling within the functional genus. While experimentation may be necessary to identify compounds falling within the functional genus, such experimentation would not be undue. By requiring that the claims define each genus structurally rather than functionally, the Office will create an inappropriate avenue for third party circumvention of those claims.

Nonetheless, to facilitate prosecution Applicants have amended independent claims 1, 42, and 48 to provide that (a) the

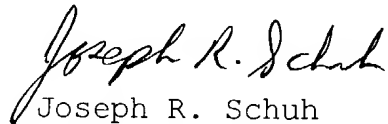
aldosterone receptor antagonist is selected from Eplerenone or spironolactone, and (b) the beta-adrenergic antagonist is selected from a specific Markush group of compounds.

Accordingly, the claims as amended should now overcome the Office's §112 rejection.

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Favorable consideration and early allowance of these claims is requested. Applicants respectfully request a three-month extension of time to and including February 11, 2004 for filing a response to the August 11, 2003 Office Action in this matter. The Commissioner is hereby authorized to charge (a) the \$950.00 fee for the requested three-month extension of time under 37 C.F.R. 1.16 and 1.17, (b) the \$180.00 fee for additional claims, and (c) any other fees that may be required during the entire pendency of this application, to Deposit Account No. 19-1025.

Respectfully submitted,



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